IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION FOR U.S. LETTERS PATENT

TITLE:

DEVICE FOR ASSISTING THE POSITIONING OF MEDICAL DEVICES

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DEVICE FOR ASSISTING THE POSITIONING OF MEDICAL DEVICES

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims priority to U.S. Provisional Patent Application No. 60/528,505 filed December 10, 2003, entitled DEVICE FOR ASSISTING THE POSITIONING OF MEDICAL DEVICES, the disclosure of which is hereby incorporated by reference in its entirety.

TECHNICAL FIELD

[0002] This invention relates to medical positioning devices and more particularly to systems and methods for using imaging equipment, such as ultrasound, for assisting in the placement of a medical device.

BACKGROUND

[0003] Proper positioning of medical devices, such as needles, catheters, drills, saws and even scalpels, is critical in the proper performance of certain medical procedures. Often the surgeon must look at a screen while trying to manually position a medical device, and thus can not look directly at the device. This is difficult at best and sometimes results in improper angles of attack and could result in improper placement of the medical device.

SUMMARY

[0004] In one embodiment, a needle guide is attached to the end of an ultrasonic probe in a manner such that the needle will follow a known trajectory under control of the needle guide. The surgeon then positions the needle guide by looking at the ultrasound image formed from the ultrasound radiated from the probe.

[0005] In one embodiment, the needle guide has a release mechanism that allows the needle (or other medical device) that had been positioned in the guide to remain in the patient when the probe is removed.

[0006] In one embodiment, the needle guide is designed to be releasably mounted to a bracket which, in turn, is releasably mounted to the end of the probe.

[0007] The foregoing has outlined rather broadly the features and technical advantages of the present invention in order that the detailed description of the invention that follows may be better understood. Additional features and advantages of the invention will be described hereinafter which form the subject of the claims of the invention. It should be appreciated that the conception and specific embodiment disclosed may be readily utilized as a basis for modifying or designing other structures for carrying out the same purposes of the present invention. It should also be realized that such equivalent constructions do not depart from the invention as set forth in the appended claims. The novel features which are believed to be characteristic of the invention, both as to its organization and method of operation, together with further objects and advantages will be better understood from the following description when considered in connection with the accompanying figures. It is to be expressly understood, however, that each of the figures is provided for the purpose of illustration and description only and is not intended as a definition of the limits of the present invention.

DESCRIPTION OF THE DRAWINGS

[0008] FIGURE 1 shows one embodiment of a probe having a medical device positioning guide mounted thereon;

[0009] FIGURE 2 shows a view of the positioning guide of FIGURE 1;

[0010] FIGURE 3 shows one embodiment of a medical device guide and release mechanism based on the embodiment of FIGURE 1;

[0011] FIGURE 4 shows one embodiment of a needle held by the medical device guide;

[0012] FIGURE 5 shows details of one embodiment of the release mechanism based on the embodiment of FIGURE 1;

[0013] FIGURE 6 illustrates how the release mechanism of FIGURE 5 releasably mates with the device guide of FIGURE 1;

[0014] FIGURES 7A, 7B and 7C illustrate the releaseable mating of the device bracket with the probe;

[0015] FIGURE 8A, 8B and 8C illustrate the releaseable mating of the device guide with the device bracket;

[0016] FIGURES 9A, 9B, 9C and 9D show dimensional relationships of embodiments of the illustrated device guide;

[0017] FIGURES 10A, 10B and 10C show dimensional relationships of embodiment of the illustrated release mechanism; and

[0018] FIGURE 11 shows one embodiment of packaging a plurality of device guides; and

[0019] FIGURES 12 and 13 show alternate embodiments of the medical device guides.

DETAILED DESCRIPTION

[0020] FIGURE 1 shows one embodiment of probe 10 having bracket 12 releasably attached thereto. This attachment, for example, is by fitting a first side 71 of the bracket over protrusion 13 on probe 10, as shown in FIGURE 7A. The other side 72 of the bracket fits over the other side 15 of probe 10 as shown in FIGURE 7B, and locks between protrusions 73 and 74 up against slot 14 of probe 10 again, as shown in FIGURE 7C. Slot 702 snaps over protrusion 13 to hold bracket 12 from swinging open. Probe 10, in the embodiment of FIGURE 1, can be an ultrasound probe.

[0021] In operation, probe 10 (FIGURE 1) sends ultrasound signals into the body and these signals then provide images of organs, fluids, etc which are otherwise hidden from view. When the probe is positioned properly, as determined by the images sent back by the ultrasound, the surgeon can then insert a needle, such as needle 41, (or other surgical instrument), knowing the instrument's trajectory based upon the received images. The trajectory is a preset by the selection of the device guide. The device guide establishes an angle of attack with respect to the proximal end of the probe. By extension, this angle of attack extends below the skin of the patient. In some cases, the image may contain a projection of the needle trajectory as an aide to the surgeon.

[0022] When the needle, or other device to be inserted, is positioned properly, the needle is slid forward so that its proximal end moves toward the patient and enters the patient. When the desired depth is reached, mechanism 50 is operated to release the needle thereby allowing probe 10, bracket 12 and needle guide 20 to be removed, leaving the needle (or other device) within the patient's body.

[0023] FIGURE 2 shows bracket 12 having medical device guide 20 mounted thereon. Note that device 20 and device 12 can be a single structure if desired. Device 20 in the embodiment shown, is a device for holding a needle (shown in FIGURE 4) within groove 22. Release control portion 50 holds the needle in position, while end portion 51 serves to release the needle when the needle has been properly positioned. If device 20 and device 12 are separate structures, they can be releasably mated as shown in FIGURES 8A and 8B. As shown in FIGURE 8A, one end of device 20 is mated via pins 82 (shown in FIGURE 8C) being inserted into bracket 82. Once pin 83 is positioned in bracket 82, guide 20 is rotated toward probe 10 and snaps in position under control of tab 81 of bracket 12 releaseably locking on edge 21 of device 20.

[0024] As shown in FIGURE 3, device guide 30 consists of two parts: namely, guide 20 and release mechanism 50. Guide 30 snaps into bracket 12, as discussed above, attached to an ultrasound transducer. The device guide is manufactured to control the placement of devices, such as catheter and needles, to multiple depths, by changing the angle of attack at which the needle (or catheter) is presented to the transducer. The device guide is also manufactured to handle multiple gauges to accommodate specific diameter medical devices.

[0025] As shown in FIGURE 4, guide 20 has lead-in 43 to make insertion of the needle (such as needle 41) into the guide easier. Needle 41 then rests in channel 44 along the longitudinal axis of probe 10 so that the needle is positioned in a specific trajectory with respect to the surface to be probed. In effect, the medical device (which typically would be an elogated device (needle) with a substantially round cross-section forms a closing angle with the proximal end of the guide (and the probe) so that when the probe is properly placed, the proximal end, when moved down the channel, will be positioned a given distance below the skin of the patient. This trajectory intersects the patient at the target depth (such as 1.5 cm.) as indicated on the needle guide. Various angles and respective depths for 1.5, 2.5, 3.5 and 4.5 cms are shown in FIGURE 9A-9D.

[0026] FIGURE 4 shows mechanism 50 (discussed in more detail with respect to FIGURES 6 and 7) mounted in slot 45 of guide 20. Release portion 52 is positioned over needle 41 and exerts pressure on needle 41 within groove 44. The pressure from portion 52 on the needle guide keeps the needle in proper orientation, but allows the user to slide the clamped needle toward the patient. The needle can then be positioned below the skin of the patient at the desired depth.

[0027] FIGURE 5 shows mechanism 50 having flexible tab 55 to maintain a closed position and to prevent accidental opening. The geometry of mechanism 50, including dimension D, provides a specific amount of needle drag friction between the inserted needle and groove 44. Once the needle has been oriented into the desired position, tab 55 is flexed inward allowing mechanism 50 (and particularly overhang 52) to move away from groove 44, thereby allowing needle 41 to release from the device guide. This, then, allows needle 41 to remain in the patient when the probe is removed.

[0028] FIGURE 6 shows a top schematic view of mechanism 50 inserted in guide 20 with tab 55 locking against edge 42 of guide 20 prior to release of mechanism 50 from guide 20. Tab 55 flexes into slot 53 formed by opening 54.

[0029] FIGURES 9A-9D show dimensional relationships of embodiments of a device guide. FIGURE 9A shows a top view of guide 20. FIGURE 9B is an end view of guide 20 and FIGURE 9C is a section 9C-9C taken through device 20 in FIGURE 9B. FIGURE 9D shows typical illustrative dimensions (keyed to FIGURE 9C) for different depth guides.

[0030] FIGURE 10A shows a top view of mechanism 50. FIGURE 10B shows the end view of mechanism 50 and FIGURE 10C is a section 10C-10C taken through mechanism 50 in FIGURE 10B. Dimension D is keyed to the diameter of the device to be held within the guide. For 18 gauge needles, this dimension would be .070 in for the embodiment shown, and dimension D1 would be .096 in. A typical length for mechanism 50 would be 0.564 in. If desired, portion 501 (FIGURE 10C) can be tapered to better wedge needle 41 when in seating portion 44 of the guide.

[0031] FIGURE 11 shows one embodiment 1100 of the packaging for a plurality of needle guides, 50, 1110, 1111 and 1112. Each of the needle guides can have different target

depths, or they can all have the same depth. Center holder 1101 has limbs 1102 for holding each guide. Any number of limbs can be used.

[0032] FIGURE 12 shows one alternate device guide 1200 with latch 1201 in the open position. As shown, latch 1202 will engage protrusion 1203 for latching purposes.

[0033] FIGURE 13 shows guide 1200 in the latched position clamping needle 41 in position.

[0034] Although the present invention and its advantages have been described in detail, it should be understood that various changes, substitutions and alterations can be made herein without departing from the invention as defined by the appended claims. Moreover, the scope of the present application is not intended to be limited to the particular embodiments of the process, machine, manufacture, composition of matter, means, methods and steps described in the specification. As one will readily appreciate from the disclosure, processes, machines, manufacture, compositions of matter, means, methods, or steps, presently existing or later to be developed that perform substantially the same function or achieve substantially the same result as the corresponding embodiments described herein may be utilized. Accordingly, the appended claims are intended to include within their scope such processes, machines, manufacture, compositions of matter, means, methods, or steps.